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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,371	03/26/1999	DAVID LANE	4-20937/A/PC	8832

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SAM.

Office Action Summary	Application No.	Applicant(s)	
	09/214,371	LANE ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-46 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-46 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 11-21-03.

Claims 27-46 and 52 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claims 41-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting DM2 protein binding to p53 in vitro comprising contacting DM2 protein with a polypeptide comprising SEQ ID Nos: 4, 6-8 and 10-14, does not reasonably provide enablement for methods of inhibiting the binding of DM2 and p53 in vivo comprising contacting DM2 protein with a polypeptide comprising SEQ ID Nos: 4, 6-8 and 10-14, nor for the purification of a binding partner of a compound in vitro or in vivo comprising contacting a compound comprising SEQ ID No: 4, wherein DM2 and p53 binding are inhibited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed 11-21-03 have been fully considered but they are not persuasive. Applicants argue that the pending claims are not drawn to in vivo applications because they make no reference to in vivo administration. Contrary to Applicants' assertions, the claims do read on in vitro, as well as in vivo applications.

Because the claims are silent regarding the particular scope (e.g. in vitro or in vivo), the claims are read in light of the broadest interpretation, and here the broadest interpretation encompasses in vivo, as well as in vitro, DM2 and p53 binding inhibition upon administration of the polypeptides claimed.

Applicants argue further that no reasonable basis has been provided to support the conclusion that the instant disclosure would not enable the full scope of the claims, including the in vivo administration and subsequent inhibition of DM2 and p53 binding by the polypeptides claimed, as well as the ability to purify a binding partner using the method described in claims 43-46. It would require undue experimentation beyond the guidance provided in the instant specification to determine the appropriate means of delivery, dosage and concentration to inhibit DM2 and p53 binding in appropriate target cells in any organism comprising administration of the polypeptides claimed. The instant specification teaches the ability to inhibit DM2 and p53 binding extracts in vitro following administration of the polypeptides claimed. The results achieved in vitro, using purified proteins in defined solutions, are not representative or correlative of achieving such binding inhibition in a target cell in vivo. This would require undue experimentation beyond that taught in the instant disclosure.

In addition, it is unclear how a binding partner is identified and purified, either in vivo or in vitro, utilizing the method set forth in claims 43-46. No guidance has been provided in the instant specification for the identification and subsequent purification – in vitro or in vivo - of any binding partners upon inhibition of DM2 and p53 binding using the polypeptides claimed. This would require undue experimentation beyond that

taught in the art, and beyond that taught in the instant specification. The successful inhibition of binding of two previously characterized proteins in a defined system in vitro is not representative or correlative of the ability to identify and successfully purify any binding partners using the polypeptides claimed. Therefore, the scope of enablement rejection is maintained.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43, line 12, it is unclear what is meant by the phrase "and inhibits the binding of said DM2 protein to a p53 protein, with a binding partner of said compound." Appropriate clarification is requested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-46 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Please note that the written description rejection of record in the previous Office action, which addressed the amino acid motifs encompassed by SEQ ID Nos: 4, 10 and 11, has been withdrawn in light of Applicants' arguments, filed 11-21-03. A new written description rejection, which addresses the very broad genus encompassing **compounds** that further comprise the amino acid motifs claimed, is set forth below.

The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising **compounds** that bind to DM2 protein, and which further comprise the amino acid sequences claimed. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising cyclic lactams (e.g. this reads on non-amino acid structures such as uric acid). The scope of the claims includes numerous structural variants, and the genus is highly variant, because a significant number of structural differences between genera members if permitted. Concise structural features that could distinguish compounds within the various genera from others are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genera comprising **compounds**, or comprising compounds further comprising amino acid motifs comprising cyclic lactams, and because the genera are highly variant, the description provided is insufficient. One

of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the very broad genera comprising **compounds** further comprising the amino sequences claimed, and optionally further comprising cyclic lactams. Thus, Applicant was not in possession of the broad genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 27, 28, 38, 41, 42 and 52 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al.

Lee et al (Gene, 184: 177-183 1997) teach compositions comprising polypeptides of SEQ ID NO: 4 and their inhibition in vitro of DM2 and p53 binding, and which compositions comprise a pharmaceutically acceptable carrier (See accompanying sequence alignments, and see figures 1 and 2 in Lee et al).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

February 21, 2004

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER